U.S. FOOD & DRUG ADMINISTRATION

Transforming Drug Development and Regulatory Assessments: Is it Possible?

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Disclaimer

The views and opinions presented here represent those of the speakers and should not be considered to represent advice or guidance on behalf of the U.S. Food and Drug Administration.


We Charted Our Course
We're Ready to Go
We're on Our Way
We Are Here
What's Next?

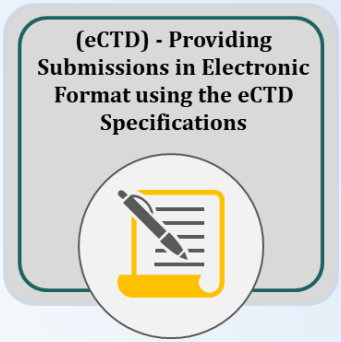
FDA recognizes the need to improve efficiencies and encourages the use of standardized data

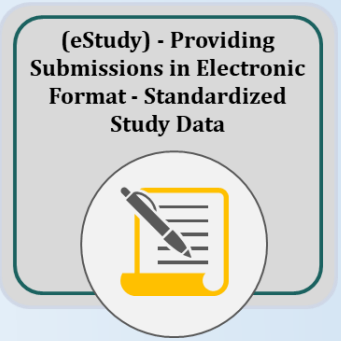
CDISC standards are developed

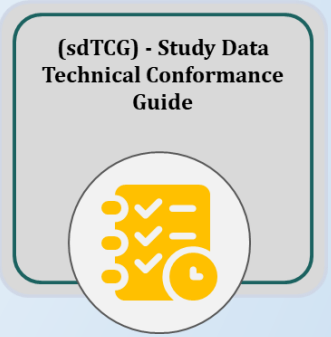
FDA encourages submission of SDTM and ADaM

And ….SEND

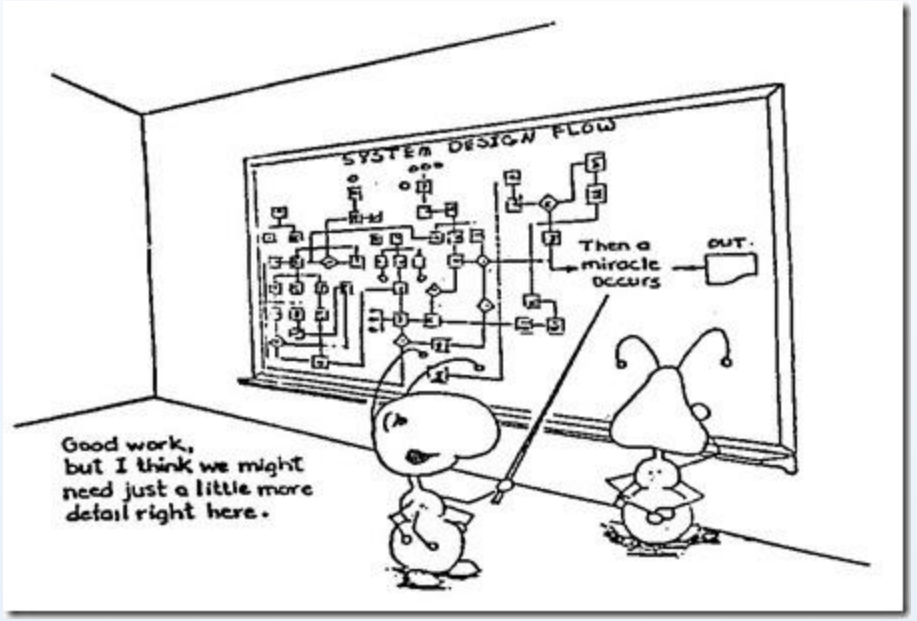
- 2012 FDASIA, Title XI Section 1136
- 2014: Providing Regulatory Submissions in Electronic Format
- 2014: Providing Regulatory Submissions in Electronic Format: Standardized Study Data
- 2014: Study Data Technical Conformance Guide and Data Standards Catalog







https://www.fda.gov/industry/fda-data-standards-advisory-board/study-data-standards-resources


SYSTEM DESIGN FLOW
Then a miracle occurs
OUT.
Good work, but I think we might need just a little more detail right here.

Optimizing the Use of Data Standards

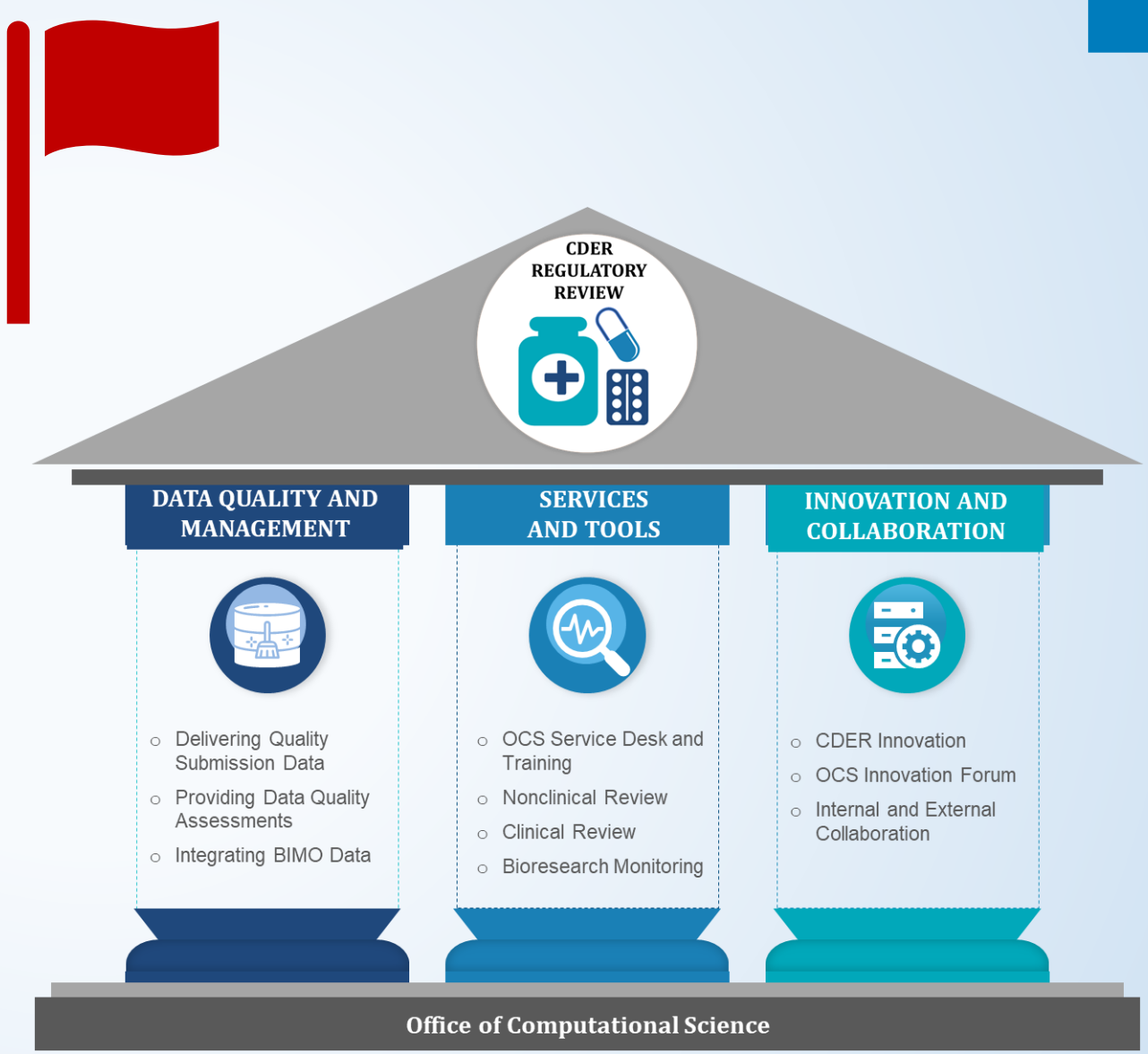
- Clinical Integrated Study Data and Analysis Data Reviewer's Guide
- Best Practices in Data Standards Implementation Governance
- SDTM ADaM FAQ Implementation
- Management of ODS Regulatory Referenced Deliverables
- Implementation of Estimands (ICH E9 (R1)) using Data Standards

Nonclinical Topics

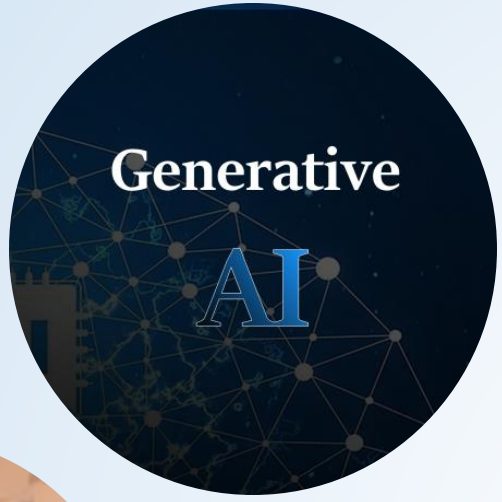
- SEND Implementation User Group
- SEND Industry Feedback Survey
- Conformance with the tumor.xpt Specification
- Harmonization of SEND Implementation to Enable Historical Control Data Analysis
- Nonclinical Protocol Automation
- Nonclinical Scripts
- Nonclinical Study Data Reviewers Guide

https://advance.phuse.global/display/WEL/Working+Groups

- Office of Computational Science offers services, training and Service Desk support
- Reviewers prepared to embrace electronic data



Study Data Standards Resources



- New paradigm of drug development and clinical research
- New paradigm in regulatory review
- How do we use technology?
- How do we collaborate?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